

Appln. No. 10/518,950
Amdt. Dated May 27, 2009
Reply to Office Action of November 28, 2008

REMARKS

Entry of the foregoing amendment and reconsideration of this application are requested. Claim 1 has been amended and claims 1-36 remain pending in the application.

Applicant acknowledges the conditional allowance of claims 30 and 31 if rewritten in independent form to include all limitations of the base claim and any intervening claims. Applicant reserves the right to rewrite these claims in allowable form as suggested once reconsideration has been made of claim 1 as amended herein.

Claims 1-8, 16-29, and 32-36 were rejected under 35 USC §102(b) as being anticipated by Pearson et al US Patent No. 5,658,259. Claims 1-8, 16-25, 28, and 32-36 were also rejected under 35 USC §102(e) as being anticipated by Heiniger US Patent No. 6,773,415. Also, claims 9-15 were rejected under 35 USC §103(a) as being unpatentable over Pearson et al or Heiniger in view of Sudnak US Patent No. 4,894,055.

The Examiner has copied substantial portions of claim 1 and various claims dependent therefrom of the present application, and has imported reference numerals into these claims, taking those numerals from Pearson et al or Heiniger as set forth in paragraphs 4 and 5 of the Office Action. For reasons set forth below, it is explained why these rejections should not be sustained.

Applicant believes Pearson et al and Heiniger are the primary references relied upon by the Examiner in the anticipation and obviousness rejections. As a result, applicant believes distinguishing the claims over Pearson et al and Heiniger will obviate all rejections. Accordingly, the following arguments are directed towards distinguishing the present claims over Pearson et al and Heiniger.

Pearson, Heiniger and Liversidge are all concerned with protecting users of medical needles, and indeed others who may be exposed to those needles, from accidental needle-stick injuries, particularly after the needle has been used to undertake a medical

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procedure. This is a serious problem which modern health and safety requirements demand be fully addressed to protect all those who could come into contact with a used needle.

In addition to the above, there is also a requirement to protect the tip of a needle prior to its use for medical purposes. Current hypodermic needles are of very small diameter and are finished to be extremely sharp, which makes the tip of the needle susceptible to minor damage. If damaged, an injection is very much more painful than otherwise is the case.

Further, many patients have a considerable fear of needles and the mere sight of a needle can cause distress. For this reason alone, there is a case for covering a needle before use, with the needle being exposed only as the injection is being performed.

Against the above background, the invention of Liversidge is a safety device for a medical needle which allows the needle to be fully covered both before its use for performing a medical procedure and after that use. Further, following the use, the sleeve which covers the needle is fully automatically locked in its protecting position such that short of destroying the device, the needle cannot be exposed once more, thereby obviating needle-stick injuries.

Though claim 1 of Liversidge as first presented for examination allowed for the sleeve 16 (or the corresponding sleeve of the other embodiments of Liversidge) not necessarily wholly covering the needle in the initial position, claim 1 has now been amended so as to make it a positive requirement that in the initial position, the sleeve fully covers the needle. Claim 1 also specifies that the protecting position of the sleeve is the same as the initial position; that is, the sleeve starts at and ends up at the same axial position relative to the needle. Achieving the above is actually a very difficult problem to solve. If the final (protecting) position of the sleeve is the same as the initial position and the sleeve is locked out when the sleeve is in its final position, a simple locking arrangement (for example, some kind of pawl interengageable with an abutment on the sleeve, or an equivalent mechanism)

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will lock the sleeve in its initial position as well. Such a device would not be useful and so the initial position of the sleeve must be spaced rearwardly from its final position to prevent unwanted locking. All passive safety devices (as explained in the specification) must be capable of operating without human intervention and for this purpose, the sleeve is spring-urged forwardly. To prevent the sleeve moving to its final locked position before it has been used, the device must include something to arrest the sleeve at its initial position short of its final position, to prevent locking-out before use. Then, on use of the device, movement of the sleeve from its initial position has to cause something to happen within the mechanism of the device, so that when the sleeve is moved under spring forward towards its final position, it may pass its initial position and then be locked out in the final position.

Referring now to Pearson, Figs. 1-4 relate to a first embodiment and Figs. 5-7 to a second. In the case of the second embodiment, there is no locking of the needle cover member 238 by any kind of "locking member which projects forwardly from the support". Locking of the needle cover member (the sleeve of Liversidge) in Pearson is achieved by spring 240 (see Figs. 6 and 7) carried in groove 250 of the needle cover member. The Pearson spring expands radially into groove 252 of the needle housing member 234 when the needle cover member has slid forwardly sufficiently under the action of spring 260.

In rejecting claim 1, the Examiner doubtless is referring to the first Pearson embodiment of Figs. 1-4. Here, the needle has a hub assembly 30 (see column 4, lines 39-51) and is supported in central peripheral portion 33 of the narrowed forward portion 32 of the hub assembly, and not in a "support 43" as indicated by the Examiner in paragraph 4 of the Office Action.

The embodiment of Figs. 1-4 of Pearson has a tubular leaf spring element 110 which is fixed in relation to the housing. Column 6, lines 27 et seq disclose "the spring element is cylindrical except for . . . a spring tab member 114 cut into the forward portion of the spring element. The tab member 114 extends forwardly and inwardly from its rearward

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end to its forward end and has its forward end disposed in resilient, spring biased engagement with an exterior surface 116 of the needle cover 40."

So neither the left spring element 110 nor tab 114 satisfy the limitations in claim 1 for the blocking member. The element 110 does not move because it is fixed in relation to the housing. The tab 114 is curved inwardly as described and illustrated in the non-blocking position, and when in the blocking position, has essentially the same form as in the non-blocking position, though careful study of the drawings show that the tab 114 is actually curved inwardly to a slightly lesser extent when it blocks movement of the cover, as the cylindrical surface rearwardly of surface 120 appears to be of a slightly greater diameter than surface 116 on which the tab bears before locking the needle cover.

Tab 114 is formed as a spring solely to allow the forward end to ride over flange 118. Before and after locking of the needle cover, it is in substantially the same position with respect to the body of the device.

There is no control means within the meaning of claim 1. Radial surface 120 (referred to by the Examiner in paragraph 2 of the Office Action, page 3) does not in any way control the movement of the tab 114. It merely provides an abutment surface for engagement by the tab 114 once the needle cover has moved sufficiently forwardly for the forward end of the tab to ride over flange 118 and then return more or less to its original position.

The above arguments represent the important structural differences from which it can be seen that the device of Pearson is quite different from that of Liversidge. But there is a much more important functional difference as indicated above, and as defined in claim 1 in the second paragraph starting "a sleeve mounted . . .". Specifically, the needle cover does not have an initial position **and** a protecting position **corresponding to the initial position**. A comparison with Figs. 2 and 4 of Pearson (showing the initial and protecting positions) with Figs. 1A and 1E of Liversidge immediately makes this difference wholly clear, and

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conveniently a datum line appears in many of the groups of figures of Liversidge, including Figs. 1A to 1E.

In any event, a comparison of Figs. 2, 3 and 4 of Pearson shows that in the initial position, a flange 104 (only referenced in Fig. 1) at the forward end of the needle cover 40 is in engagement with sheath 44 and the needle tip is spaced rearwardly of the flange 104 by a relatively small distance. Fig. 3 shows an intermediate position where an injection is being performed, and Fig. 4 the final position at the completion of an injection procedure. Here, there is a significant clearance between the forward end of the sheath and the flange 104 of the needle cover. The needle tip is spaced rearwardly of the flange 104 by a much greater distance than in Fig. 2. Thus, contrary to the limitation of claim 1 of Liversidge, the position of the needle cover in the initial and final (protecting) position is **not** the same relative to the needle, let alone to the body of the device.

The above is not just a trivial technical argument; it is fundamental to the different kinds of the device and demonstrates that they work in completely different ways.

Pearson is an example of a simple pawl interengageable with an abutment on the sleeve as referred to herein. In Pearson, the tab 114 is the pawl. Pearson "works" because the protecting position of the needle cover (sleeve) is forwardly of its initial position. So too is the needle forwardly of its initial position. That is because Pearson relates to a different kind of device from that of Liversidge. Pearson concerns an auto-injector where a vial of anesthetic is discharged into a needle pushed into the flesh of a patient all done fully automatically on pressing the release button. By contrast, the device of Liversidge is concerned with protecting the needle of a pre-filled syringe and making safe the needle after use. It is submitted that Pearson does not anticipate claim 1 of the present invention.

Turning now to Heiniger, this reference also describes a sliding sleeve 1 which is able to shield a needle, both before and after an injection procedure. A locking ring 11 is

slidably mounted within the sleeve 1, and has clips 2 bearing against the inside surface of the sleeve 1. The locking ring 11 moves rearwardly with the sleeve 1 and then catches behind locking protrusion 9 on a canular support 3. Then, on subsequent forward movements of the sleeve 1, the clips 2 catch behind stays 10 so as to lock the sleeve in its forward position. As will be appreciated, even with very fine tuning of the component parts, there will be significant friction between the clips 2 and sleeve 1, and also at the precise moment the needle fully penetrates the patient, the ring 11 must ride over the locking protrusion 9 so as to be retained in its rearward position. These features will make the device difficult to use.

Much more importantly, the locking ring 11 does not in any way satisfy the limitations in amended claim 1 as to the blocking member and the control means. The blocking member always extends axially and at no time takes up an acute angle to the axis of the device. Further, no "control means" within the meaning of Liversidge claim 1, can be identified in Heiniger. Even if it could be argued that the control means was the interaction of the ring 11 and locking protrusion 9, that interaction occurs only when the ring 11 has moved fully rearwardly and so the control means cannot "maintain the blocking member in its non-blocking position during movement of the sleeve from its initial position to its retracted position" as required by claim 1.

As Heiniger does not possess these important features of amended claim 1, it cannot be maintained that Heiniger anticipates Liversidge.

Having regard to the fact that both Pearson and Heiniger relate to different kinds of a device as compared to Liversidge and do not anticipate claim 1 (as amended above) equally, it cannot be argued that the subject matter of claims 9-15 is unpatentable over Pearson or Heiniger in view of Sudnak (US 4,894,055). Sudnak concerns a very simple spring loaded sleeve again of the simple pawl kind discussed above and would give no teaching to a designer seeking to improve the kind of device described in either Pearson or Heiniger, in reaching the invention of Liversidge where a blocking member starts aligned

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with the axis of the device, is maintained aligned with that axis during rearward movement of the sleeve and then is released for movement to its blocking position where the blocking member lies at an acute angle to the axis of the device so as thereafter to block rearward movement of the sleeve.

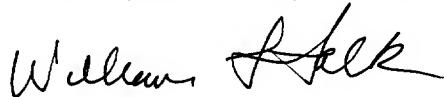
Based on the foregoing arguments, it is believed that claim 1, as well as claims 2-36 which are ultimately dependent on claim 1, are allowable over the cited prior art. Accordingly, the Examiner is requested to pass this application to issuance with claims 1-36 being deemed allowable.

In maintaining the duty of disclosure, applicant is disclosing the following co-pending applications:

<u>Application No.</u>	<u>Filing Date</u>
12/442,139	03/20/2009
12/160,046	07/03/2008
11/722,983	06/27/2007
11/675,743	02/16/2007
10/589,122	08/10/2006

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP



William L. Falk
Reg. No. 27,709

100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
Telephone No. (414) 271-7590
Attorney Docket No.: 1926-00102